

Appl. No. 10/058,540
Amdt. dated December 13, 2004
Reply to Office Action of October 15, 2004

REMARKS/ARGUMENTS

Claims 47 – 66 stand allowed.

The remaining claims at bar, namely Claims 1 – 11 were rejected in the Examiner's latest October 15, 2004 Office Action. Applicant has amended independent Claims 1 and 8 and Claim 5 dependent on Claim 1. Previously dependent Claims 2, 4, 6, 7, 9, 10 and 11 remain as previously presented. It is believed that the amended claims now recite language that clearly distinguishes over the prior art of the Page et al '522 patent cited by the Examiner in both structure and function.

It is absolutely clear that the suction control valve of the relied upon Page et al patent will not function when used as part of a closed tracheal suction system that is attached to a positive air pressure ventilator. Page et al insists that his valve be used in a non-ventilator attached open type aspirating device (see Abstract; Prior Art, Column 2; and Brief Summary of the Invention, Columns 1 and 2). A closed system is used in conjunction with a ventilator. An open system (Page et al type) is not used in conjunction with a ventilator.

A closed system must maintain PEEP (positive end expiratory pressure), and the suction control valve absolutely must maintain that positive pressure or risk loss of vital positive pressure air to the patient (see the present

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invention, Pages 2, 4, 9, 12 and 13). The Page et al prior art suction control valve structure is simply not capable of performing as a component in the closed tracheal suction system of the present invention because there is no teaching of a valve structure that will prevent any loss of positive pressure out the valve structure to atmosphere to form a 100% positive air pressure proof airtight slideable seal. Positive pressure from the ventilator can exceed 2psi, and Page et al teaches no structure to withstand this positive pressure when the valve is in its normally positioned closed position. How can the Page et al valve with a valve plate 286 loosely fitted into the valve body slot 208 be a structural teaching of a seal capable of withstanding and maintaining PEEP? It simply cannot.

Also, Page et al shows no means to prevent any leakage of fluid and positive pressure airflow through the valve when the valve remains attached to a source of suction. In the present invention, "plunger 16 and piston 19 have slightly oversized sidewalls 21 which resiliently expand outward to form a 100% leak proof airtight hermetic seal within central passageway 13 and further act to seal off any leakage of suction or secretions out the valve 10 even if the valve 10 is left attached to a source of vacuum or suction such as leaving the valve connected to suction tubing" (see Page 9 of applicant's Specification). In

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addition, the present invention teaches the use of a built-in molded wiper seal "O" ring (Page 12 and Fig. 4) to prevent any loss of secretions out the valve.

Structurally, Page et al teaches a solid rectangular flat valve plate 286 loosely fitted into valve body slot 208 (Column 10, Lines 47 – 64, Figs. 7, 8 and 9). Even though Page et al says the valve is a seal as noted by the Examiner, there is absolutely no teaching of how such a seal structure can act as a slideable seal to prevent loss of positive pressure through the valve when it remains continuously attached to suction set at 300mm Hg for up to 72 hours (see applicant's present invention Page 2). In a closed tracheal suction system, a suction control valve must be normally closed and must prevent any loss of positive pressure out the valve to atmosphere, and the valve must prevent any leakage of fluid and positive pressure air flow between the suction catheter and the suction source when the closed system remains attached to a suction source.

By comparison, Page et al emphatically states that his valve can only be used in an open system such that the Page et al valve can slightly leak to atmosphere with no detrimental consequences to the patient. This is not the case in a closed system attached to a ventilator delivering positive pressure. As such, the Page et al valve cannot be a mere substitution for the uniqueness of the suction control valve of the present invention nor does Page et al anticipate the

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structure or functional performance of the High Efficiency suction control valve disclosed in the present application. In the present invention, Figs. 2, 3 and 4 along with page 9 depict and disclose a circular plunger and piston wherein the piston is hollow and has thin flexing resiliently molded oversized sidewalls 21 that resiliently expand outward to form a slideable 100% leak proof airtight hermetic seal within central passageway 13. That unique non-obvious structure wherein the piston walls are thin, oversized and come in direct slideable sealing contact with the central passageway 13 is a unique patentable structure directly opposite from Page et al which has the thick solid valve plate that is undersized and is fitted loosely into a valve slot.

Page et al further states the primary object of his invention is to provide a single use non-ventilator attached medical aspirating device (Column 2, Lines 9 – 20). Likewise, Page et al teaches a device to be used by patients that can voluntarily respirate (Column 2, Lines 25 – 28) which means non-ventilator attached (Column 2, Lines 9 – 12). The Page et al device is simply used for one single procedure on a non-ventilated patient and then discarded as part of an open catheter device. As such, the Page et al suction control valve lacks any means or structure for teaching its reuse for an extended period of time (up to 72 hours) while remaining connected to a pressurized ventilator circuit (see

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applicant's present invention, Page 4). The practical proof that the Page et al valve (Ballard Medical Products assignee) is not suitable for a closed suction system control valve is the fact that Ballard Medical itself solely uses the Palmer U. S. Patent No. 4, 569,344 suction control valve in all of its commercial Trach-Care Closed Trach Systems and not the Page et al valve.

As such, the applicant believes he has set forth clearer and more detailed remarks and arguments to overcome the Examiner's objections. The applicant has therefore amended Claims 1, 5 and 8 with language that clearly distinguishes over the prior art and recites the structural patentable subject matter. Dependent Claims 2, 4, 6, 7, 9, 10 and 11 remain as previously presented.

As such favorable consideration and allowance of the claims at bar in this application is warranted and requested at this time. However, any input from the Examiner in furtherance of the allowance of the outstanding claims is welcomed.

Respectfully submitted,

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